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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,734	12/21/2001	Shin Ikeda	43888-122	4560

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/023,734</p>	<p>Applicant(s)</p> <p align="center">IKEDA ET AL.</p>	
	<p>Examiner</p> <p align="center">ALEX NOGUEROLA</p>	<p>Art Unit</p> <p align="center">1753</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/424,715.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/07/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

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Claim Objections

1. Claims 2 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 2 and 6 each depend from cancelled claim 1.

Double Patenting

2. Applicant's filing request under 37 C.F.R. §1.53(b) of December 21, 2001 requests the instant application to be filed as a divisional application of application Serial No. 09/424,715. However, the examiner has not found a restriction request in application Serial No. 09/424,715. Thus, a double patenting rejection is not barred as "the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction." MPEP 804.01.

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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4. Claim 3 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of prior U.S. Patent No. 6,340,428 B1. This is a double patenting rejection.

5. Claim 4 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 6 of prior U.S. Patent No. 6,340,428 B1. This is a double patenting rejection.

6. Claim 5 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of prior U.S. Patent No. 6,340,428 B1. This is a double patenting rejection.

7. Claim 7 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 8 of prior U.S. Patent No. 6,340,428 B1. This is a double patenting rejection.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claim 8 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,340,428 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 5 uses a biosensor as claimed in claim 8. Applicant should note that the last paragraph of claim 8 only provides for intended use, but, nevertheless, the limitations of this paragraph are also included in claim 5.

10. Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,340,428 B1. Claim 8, from which claim 9 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because, barring a contrary showing, whether an electrode is a working electrode or a counter electrode is intended use and not a structural distinction.

11. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,340,428 B1. Claim 8, from which claim 10 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because measuring is a use step and does not further structurally limit the device of claim 8. Furthermore, step (g) of claim 5 requires measuring the current between the counter electrode and the working electrode.

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12. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,340,428 B1. Claim 8, from which claim 11 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 provides for a layer essentially composed of lecithin as claimed.

13. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,340,428 B1. Claim 8, from which claim 12 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 of U.S. Patent No. 6,340,428 B1 provides for a hydrophilic polymer in the reaction layer.

Claim Rejections - 35 USC § 112

14. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. No support in the original disclosure has been found for locating the working electrode closer to the sample solution supply port than the counter electrode. Note that applicant has submitted the instant application as a divisional application and not as a continuation-in-part (filing request under 37 C.F.R. §1.53(b) of December 21, 2001).

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15. Claims 2, 6, 7, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a) Claims 2 and 6 are indefinite because they depend from cancelled claim 1;
- b) Claim 7, line 2 has limitations concerning "a biosensor" rather than
said biosensor --. Does this mean a biosensor structurally different than that of claim
3 is being used? Does this mean that two biosensors are being used?
- c) Claim 10: how does a measuring step further structurally limit the device of claim 8?

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 8-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yoshioka et al. (US 5,264,103). See Figures 1-3; the abstract; col. 6, ll. 21-66; col. 14, ll. 16-24; and col. 13, ll. 10-15 and col. 15, ll. 5-19. For claim 9 note that barring a contrary showing, whether an electrode is a working electrode or a counter electrode is intended use and not a structural distinction. For claim 10 note that measuring is a use step and does not further structurally limit the device of claim 8

Specification

18. The specification should be 150 words or less. MPEP 608.01(b).

Priority

19. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 27 January 1998. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b). A certified copy of Hei 10-013957 has not been found in the parent application Serial No. 09/424,715.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguera

Alex Noguera

02/21/04

Primary Examiner

Tc 1753